

**UNITED STATES DISTRICT COURT
THE WESTERN DISTRICT OF TENNESSEE
EASTERN DIVISION**

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
vs.)	No: 19-cr-10040
)	
ANDREW RUDIN, et al.)	
)	
Defendant.)	

**RESPONSE IN OPPOSITION TO MOTION TO DISMISS, FOR DISCLOSURE OF
GRAND JURY MATERIALS, AND FOR A STATUS CONFERENCE TO CONSIDER A
DELAY IN THE TRIAL DATE**

In a new motion to dismiss [Doc. 240] Defendant Andrew Rudin claims that this Court should reconsider arguments it in part rejected in a prior order [Doc. 125] denying his first motion to dismiss. Rudin’s principal argument is that *Ruan v. United States*, 142 S. Ct. 2370 (2022), changed the pleading standards in indictments against medical providers accused of illegally prescribing opioids and the Indictment returned against him [Doc. 4] is now deficient under *Ruan*. He also tries to use *Ruan* to obtain certain grand jury materials [Doc. 240 at 5] and to potentially delay the November 7, 2022 trial date. [Doc. 243]

Rudin misreads *Ruan*. That case specifically and repeatedly stated it *did not* change what Government must allege in an indictment against a medical provider accused of illegal controlled substance prescribing. Instead, *Ruan* clarified the *mens rea* standard the Government must prove *at trial* to establish such a violation. And regardless, *Ruan*’s standard for trial proof—namely, that a medical provider distributed a controlled substance knowing or intending that it was not medically authorized—was alleged in the Indictment here.¹ *Ruan* also provides no basis for

¹ *Ruan* also did not parse the language of the Conspiracy Statute, the only count under which Rudin is charged. Therefore, any impact on Rudin’s case is solely derivative of the impact on his co-

Rudin's request for grand jury testimony or to further delay trial in a case that was indicted over three years ago. This Court should deny Rudin's late-breaking motions, and this straightforward illegal prescribing case should proceed to trial on November 7, 2022.

BACKGROUND

On April 15, 2019, Rudin was charged alongside Nurse Practitioner Jeffrey Young and Dr. Alexander Alperovich² in connection with these defendants' roles at Preventagenix, a purported clinic in Jackson, Tennessee. The Indictment alleges that Nurse Practitioner Jeffrey Young, by writing prescriptions at Preventagenix, "did intentionally and knowingly unlawfully distribute" controlled substances, including Oxycodone and Hydrocodone, "not for a legitimate medical purpose and outside the course of professional practice" in violation of 21 U.S.C. § 841 (the "Distribution Statute"). The Indictment alleges specific instances of Young's knowing, unlawful distribution of these substances, including prescribing to a pregnant woman. [Doc. 4, Counts Two through Fourteen]. It details Young's use of these unlawful prescriptions to achieve publicity, fame, and sex. [Doc. 4, Count One, ¶ 25]. It also alleges that Preventagenix itself was a "Drug-Involved Premises," that is, a facility used or maintained "for the purposes of distributing Schedule II Controlled Substances outside the course of professional practice and without a legitimate medical purpose," in violation of 21 U.S.C. § 856 (the "Drug-Involved Premises Statute") [*Id.*, Count Fifteen, ¶ 40].

In contrast, Defendant Rudin is not charged under the Distribution Statute or the Drug-Involved Premises Statute. Instead, he is charged in Count One with *conspiring with Young* to

defendant Jeffrey Young's case. But, as set forth herein, *Ruan* did not change the pleading standard and in any event, the charges against Young meet the *Ruan* standard for trial.

² Dr. Alperovich pled guilty to a related Information and will not be proceeding to trial.

violate the Distribution Statute in violation of 21 U.S.C. § 846. [*Id.*, ¶ 19, et. seq., the “Conspiracy Statute.”].

Specifically, under the Rules of the Tennessee State Board of Medical Examiners, as a nurse practitioner, Young could not have operated his practice without registering a medical doctor as his supervisor. [*Id.*, ¶ 17]. Rudin joined the conspiracy by “purport[ing] to supervise Young,” even though he “knew that under Rudin’s supervision, Young prescribed controlled substances not for a legitimate medical purpose and outside the course of professional practice, and Rudin accepted money derived from the proceeds of the conspiracy in exchange for his purported supervision.” [*Id.*, ¶ 32].

Thus, Rudin played a crucial part in the conspiracy: he served as Young’s ostensible supervisor so the unlawful drug distribution could continue. The Indictment alleges that Rudin “did knowingly and intentionally combine, conspire, confederate, and agree” with Young to “knowingly and intentionally unlawfully” distribute controlled substances “not for a legitimate medical purpose and outside the course of professional practice.” [*Id.* ¶ 19]. The Indictment then alleges a list of dangerous and unlawful prescribing behaviors that Young engaged in under Rudin’s supervision, including prescribing drugs without monitoring for addiction, prescribing dangerous combinations of addictive drugs, and failing to properly diagnose patients (i.e., identify a legitimate medical purpose for the controlled substances he was prescribing). [*Id.* ¶ 34].

In June 2022, the U.S. Supreme Court handed down *Ruan v. United States*, 142 S. Ct. 2370 (2022), which clarifies the scienter requirement to establish a violation of the Distribution Statute at trial. In *Ruan*, the Court considered a long-debated issue related to prescription opioid convictions. An explanation of the *Ruan* decision begins with a brief orientation to Title 21, United

States Code, Sections 841, et. seq. (The “Controlled Substances Act”) as it applies to controlled substances available by prescription.

The Controlled Substances Act reads, in part, that, “except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.” 21 U.S.C. § 841(a)(1). Dispensing a controlled substance is “authorized,” and therefore excepted from the statutory prohibition, when “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a); *Ruan*, 142 S. Ct. at 2375. In other words, Congress generally outlawed *all* distributions of controlled substances, but recognized that there is a medical purpose for some of them. It entrusted medical professionals as the gatekeepers to carefully prescribe when legitimate medical purposes require their use.

This exception does not grant medical professionals *carte blanche* to prescribe controlled substances to any and all comers. *See, e.g., United States v. Moore*, 423 U.S. 122 (1975) (holding prescribers could be prosecuted under the Controlled Substances Act and noting “Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels. It was aware that [registered prescribers], who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.” (citations omitted)).

Until *Ruan*, however, there was some confusion over whether the language “except as authorized” was an affirmative element of the offense, and courts were split over whether what, exactly, the government was required to prove at trial with respect to the prescriber’s state of mind at the time the prescription was written.

Ruan addressed that specific issue holding that the “except as authorized” clause, while different from an element in some respects, was sufficiently like an element that the “knowingly or intentionally” *mens rea* applies to it. 142 S. Ct. at 2380. In other words, it clarified that the government must prove *at trial* that the person who wielded the pen on the prescription pad subjectively knew the prescription was not authorized by law; that is, not for a legitimate medical purpose in the ordinary course of professional practice.

However, *Ruan* was careful to explain that its decision had no impact whatsoever on how the government must plead the Indictment. Indeed, the Controlled Substances Act states that “[i]t shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any complaint, information, [or] indictment” 21 U.S.C. § 885(a)(1). *Ruan* cited this provision and reasoned that “Section 885 simply absolves the Government of having to allege, in an indictment, the inapplicability of every statutory exception in each Controlled Substances Act prosecution.” *Ruan*, 142 S. Ct. at 2371. *Ruan* then made the same point again in stating that “in a prosecution under the Controlled Substances Act, the Government **need not refer to a lack of authorization** [or any other exemption or exception] **in the criminal indictment.**” *Id.* at 2379 (emphasis added).

For the reasons set forth more fully below, *Ruan* does not require dismissal, delay, or production of grand jury materials.

ARGUMENT

A. The Motion to Dismiss Should Be Denied.

Ruan provides no basis for dismissal of an Indictment. Procedurally, while *Ruan* clarifies the scienter requirement for *proving* a violation of the Distribution Statute to a jury, it does not change the requirements for *alleging* such a violation. *See, e.g., Ruan*, 142 S. Ct. at 2379 (“the

Government need not set forth in an indictment a lack of authorization, or otherwise allege that a defendant does not fall within the many exceptions and exemptions that the Controlled Substances Act contains.”). In other words, the Government did not need to plead a knowing violation of the “except as authorized” requirement *at all*, much less with the specificity Rudin now demands.³

Other courts have considered this issue and have denied motions substantially similar to the one that Rudin brings in this case. For example, in an order in *United States v. Stanton*, No. 6:21-CR-19 (E.D. Ky. filed Aug. 17, 2022) (Doc. 208), which is attached here as Exhibit A, Judge Wier considered the sufficiency of a conspiracy charge under 21 U.S.C. § 846 that alleged, similar to the Section 846 charge in the indictment here, that defendants “did conspire . . . to knowingly and intentionally distribute controlled substances that were not issued for a legitimate medical purpose . . .” Ex. A at 2. Defendants in *Stanton* also raised the same argument as Rudin does here: namely, that a post-*Ruan* indictment must more specifically allege knew or intended the prescriptions were issued without a legitimate medical purpose. *Id.*

Stanton rejected this position, reasoning that “*Ruan* does not require that the indictment allege knowing and intentional unauthorized prescription practices any more specifically than is featured” in the conspiracy charge language quoted in the prior paragraph. *Id.* at 3. As support for this position *Stanton* noted that “*Ruan* focuses on what the United States must prove *at trial* to secure a valid conviction” *Id.* at 4 (emphasis in original); *see also, e.g., United States v. Spivack*, No. CV 22-343, 2022 WL 4091669, at *1 (E.D. Pa. Sept. 6, 2022) (“[T]he mens

³ *Ruan* affirmed that 21 U.S.C. § 885 is properly read as a “presumptive device” that “shifts the burden of production [of evidence of authorization] to the defendant.” *Ruan*, 142 S. Ct. at 2380 (citing *County Court of Ulster City v. Allen*, 442 U.S. 140, 157-58, n.16 (1979)). “[O]nce the defendant satisfies the initial burden of production by producing evidence of authorization, the burden of proving a [knowing or intentional] lack of authorization shifts back to the Government.” *Id.* Since questions of fact predominate this analysis, the core *Ruan* holding is not likely to significantly affect pre-trial motions.

rea language of section 841 requires the United States to prove beyond a reasonable doubt—not plead—in its criminal prosecution the defendant knowingly or intentionally acted in an unauthorized manner”); *United States v. Siefert*, No. 2:21-cr-2-DLB-CJS (E.D. Ky. filed Aug. 31, 2022) (Doc. 150) (minute order denying similar motion to dismiss drug conspiracy indictment against an owner of a pain clinic that raised the same arguments).

Further, although it is not required, the Indictment in this case *does* plead the elements that *Ruan* ultimately requires the government to prove to a jury. For example, it does so in paragraph 19 of the Indictment which refers to how defendants “knowingly and intentionally unlawfully” distributed controlled substances outside of the exception granted for prescriptions for a legitimate medical purpose. Thus, even if *Ruan* can be somehow read to change pleading standards, the Indictment is adequately pled and should not be dismissed. *Accord Stanton*, Ex. A at 3-5 (indictment allegations substantially similar to the ones at issue here were sufficient); *United States v. Taylor*, 2022 WL 4227510, at *5–6 (E.D. Ky. Sept. 13, 2022) (reaching the same conclusion on a Section 846 conspiracy alleged against medical providers and noting that a court interpreting an indictment alleging such a violation should do so “practically, liberally, and as the Supreme Court interpreted [Section 841(a)(1) in *Ruan*]”).

Finally, confusing the criminal and civil pleading standards, Rudin argues that “there is no statement of the facts or circumstances alleged to support Dr. Rudin’s knowledge or intent as to how he personally acted in an unauthorized manner or how he knowingly intended to facilitate Young doing so.” [Doc. 240 at 4].

No such factual assertions are needed. To the contrary, as this Court reasoned in denying Rudin’s first motion to dismiss, “[A]n indictment is sufficient if it, first, contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend,

and second, enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense.” [Doc. 125 at 3-4 (quoting *United States v. Anderson*, 605 F.3d 404, 411 (6th Cir. 2010))]. The allegations in an indictment are presumed to be true and evaluated in the light most favorable to the Government. *United States v. Keller*, 2009 WL 2475454 *4 (E.D. Mich. 2009); *United States v. Landham*, 251 F.3d 1072, 1080 (6th Cir. 2001) (“[C]ourts evaluating motions to dismiss do not evaluate the evidence upon which the indictment is based.”).

As set forth above, this Indictment not only pleads Young acted “knowingly and intentionally,” but also alleges that Rudin “knowingly and intentionally” joined the conspiracy. That is all that is required for purposes of pleading in an indictment. To the extent Rudin seeks to claim that there is insufficient evidence to support these charges, that is not a proper argument for a motion to dismiss, as this Court has already concluded. *See, e.g.*, [Doc. 125 at 3-5.]

B. The Motion for Grand Jury Materials Should Be Denied.

As Rudin concedes, Federal Rule of Criminal Procedure 6 “generally bars the disclosure of grand jury materials but allows an exception ‘at the request of a defendant who shows that a ground may exist to dismiss the indictment because of a matter that occurred before the grand jury,’” and further acknowledges he must show a “‘particularized need,’ including ‘grave doubt that the decision to indict’” was the result of errors. [Motion, Doc. 240 at 5-6 (citing Fed. R. Crim. P. 6(e)(3)(E)(ii) and *In re Antitrust Grand Jury*, 805 F.2d 115, 161 (6th Cir. 1986)).]

Rudin seeks grand jury materials on his speculation that the grand jury was not given any facts supporting probable cause that Young knowingly and intentionally exceeded his authorization to prescribe controlled substances. [Doc. 240 at 4]. His goal is to use these materials to challenge the grand jury’s conclusion as to probable cause of his guilt on grounds that the “grand

jury could not have been instructed properly on the *mens rea* requirements” in *Ruan* because *Ruan* was decided after Defendant Rudin was indicted.” [*Id.* at 6].

Following this logic, *any* opioid prescription case decided after *Ruan* would be subject to the breach of grand jury secrecy. Yet, if another court has provided this remedy on those grounds, Defendant Rudin did not identify it.⁴ Nonetheless, this Court need not cast so wide a net. On its face, the Indictment reveals that the grand jury found probable cause that both Young and Rudin acted “knowingly” and “intentionally,” and (even though it was unnecessary) expressly set forth the *Ruan mens rea* standard for the “authorized” exception. Thus, there can be no speculation that the grand jury indicted Defendant Rudin under the correct standard, even in light of *Ruan*. *Accord United States v. Adelglass*, No. 20-CR-605, 2022 WL 6763791, at *3 (S.D.N.Y. Oct. 11, 2022) (Rakoff, J.) (rejecting same argument for grand jury materials after determining that the indictment sufficiently alleged a “knowing” illegal prescription of opioids on the standard outlined in *Ruan*).

In any case, a defendant who has already been indicted can no longer challenge the sufficiency of the facts relied on in the grand jury proceedings. Courts universally hold that an indictment returned by a grand jury that is “fair upon its face” conclusively determines the existence of probable cause. *E.g.*, *Gerstein v. Pugh*, 420 U.S. 103, 117, n.19 (1975), *Ex parte U.S.*, 287 U.S. 241, 250 (1932), *Barnes v. Wright*, 449 F.3d 709, 716 (6th Cir. 2006), *Higgason v. Stephens*, 288 F.3d 868, 877 (6th Cir. 2002), *Lillard v. City of Murfreesboro, Tenn.*, No. CIV.A. 3:07-1036, 2009 WL 2047048 (M.D. Tenn. 2009). As the Supreme Court held in *Kaley v. United States*, “‘the whole history of the grand jury institution’ demonstrates that ‘a challenge to the reliability or competence of the evidence’ supporting a grand jury’s finding of probable cause ‘will not be heard.’” 571 U.S. 320, 328-29 (2014) (quoting *United States v. Williams*, 504 U.S. 36, 54

⁴ The undersigned is unaware of any such case, but admittedly has not done an exhaustive search.

(1992)). The Court explained that the probable cause requirement only serves a “gateway function” that is “relatively undemanding,” and there is “no ‘authority for . . . revising the judgment of the grand jury . . . [to determine] whether or not the finding was founded upon sufficient proof.’”). *Id.* at 329.

The Indictment in this case is fair upon its face. As set forth above, it tracks the language of both the Distribution Statute and the Conspiracy Statute and contains all required elements of the offense. *See Anderson*, 605 F.3d at 411. The Indictment even goes beyond what is necessary by asserting the “lack of authorization” requirement that, according to *Ruan*, “need not [be] set forth in an indictment.” *Ruan*, 142 S. Ct. at 2379.

C. No Delay for Further Briefing is Necessary.

Finally, the Court should reject Defendant’s apparent attempt to further delay this trial on the basis of a single case handed down more than three months ago. As set forth above, there is no reading of *Ruan* that requires dismissal—and multiple courts have already rejected the argument Rudin has raised. Nonetheless, there has been ample time to address any impact of *Ruan* in the pre-trial stage. It was released in June 2022, was the basis for this Court to continue this case from May 2022, and was immediately and heavily covered by bloggers and news outlets. The Defendant nonetheless waited more than 100 days to file his motion.

To be sure, *Ruan* will be important as the Court considers jury instructions, and the government is prepared to brief those issues if there is disagreement to the instructions the government proposes. But jury instructions are not yet due, and those issues are customarily resolved after the evidence comes in.⁵

⁵ In practice, *Ruan* clarified a circuit split on an issue that is frequently the subject of disagreement between defense counsel and the government in prescription opioid case. In other words, it may result in *less* need for briefing, not more.

This case has already been delayed for more than three years, with Rudin's co-defendant awaiting his trial in detention. Further, Defendant Rudin did not indicate that the co-defendant agreed with his plan to delay the trial again. [Doc. 243, ¶ 5, stating only that "Co-Defendant's Counsel is...in agreement that a Status/Report date is necessary."] There is no reason for further delay of this trial.

CONCLUSION

For the reasons stated above, the Court should deny Rudin's Motion to Dismiss the Indictment, deny his motion to continue the trial, and deny access to the Grand Jury materials he seeks.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 24, 2022, the foregoing response was filed with the Clerk of the Court using the CM/ECF System, which will send notice and constitute service of such filing, to counsel of record.

s/ Dermot Lynch

Dermot Lynch

United States Department of Justice

Criminal Division, Fraud Section

Trial Attorney